DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-107/S-011

GlaxoSmithKline
Attention: Olivia Pinkett, Ph.D., M.B.A.
2301 Renaissance Blvd.
P.O. Box 61540
King of Prussia, PA 19406-2272

Dear Dr. Pinkett:

Please refer to your supplemental new drug application dated August 20, 2004, received August 20, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lotronex® (alosetron HCl) Tablets.

We acknowledge receipt of your submissions dated January 12, 2005 (to IND 48,487) and February 17, 2005 (to NDA 21-107/S-011).

This "Changes Being Effected" supplemental new drug application provides for the following changes: 1) revisions to the CLINICAL PHARMACOLOGY, CONTRAINDICATIONS, and PRECAUTIONS sections of the Prescribing Information regarding drug interactions between Lotronex and fluvoxamine and ketoconazole; 2) revision of the Medication Guide regarding drug interactions involving Lotronex.

We completed our review of this supplemental application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and Medication Guide) and/or submitted labeling (package insert and Medication Guide submitted February 17, 2005).

Please submit an electronic version of the FPL according to the guidance for industry titled, *Providing Regulatory Submissions in Electronic Format – NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please mount individually 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-107/S-011." Approval of this submission by FDA is not required before the labeling is used.

We remind you that under 21 CFR 314.520 distribution of the drug is restricted to the conditions described in the approval letter for NDA 21-107/S-005 dated June 7, 2002.

We remind you that, under 21 CFR 314.550, after the initial 120 day period following this approval, you must submit all promotional materials, including promotional labeling as well as advertisements, at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Susan Daugherty, Regulatory Project Manager, at (301) 827-7456.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D.
Acting Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Kathy Robie-Suh
2/18/05 12:17:28 PM
signing for Dr. Joyce Korvick